IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Genentech, Inc. ("Genentech") and InterMune, Inc. ("InterMune") (Genentech and InterMune, collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, concerning Defendants' submission of Abbreviated New Drug Application No. 212759, which seeks approval from the U.S. Food and Drug Administration ("FDA") to market a generic copy of Plaintiffs' drug Esbriet® (pirfenidone) 267 and 801 mg tablets, in violation of Plaintiffs' exclusive rights held under numerous patents that Plaintiffs have listed with the FDA for Esbriet®.

2. Plaintiffs seek a judgment of patent infringement under 35 U.S.C. § 271(e)(2)(A), and the remedies provided under the Hatch-Waxman Act specified in 35 U.S.C. § 271(e)(4),

including, but not limited to, the specific remedy provided in 35 U.S.C. § 271(e)(4)(A), which provides that the Court "shall order the effective date of any approval of the drug … involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed."

PARTIES

3. Plaintiff Genentech is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, CA 94080. Genentech develops and commercializes pharmaceutical products throughout the United States, including within this judicial district, on its own behalf and on behalf of its affiliates within the Roche group of companies, including InterMune. Genentech holds New Drug Applications ("NDAs") in the United States for (i) Esbriet® capsules, 267 mg and (ii) Esbriet® tablets, 267, 534, and 801 mg. Genentech is also exclusively licensed by InterMune under the below-listed Asserted Patents, which cover Esbriet® FDA-approved formulations and its FDA-approved uses for safely and effectively treating Idiopathic Pulmonary Fibrosis.

4. Plaintiff InterMune is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, CA 94080. InterMune owns the United States patents that have been listed with the FDA in connection with the NDAs held by Genentech for Esbriet®, including, but not limited to, all the Asserted Patents listed below.

5. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454.

6. On information and belief, Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Ltd."). Teva Ltd. is a is a corporation organized and existing under the laws of the State of Israel having a principal place of business at 5 Basel Street, Petah Tikva, 49131, Israel .

7. On information and belief, Teva Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of Delaware, through its own actions and through the actions of its agents and subsidiaries, including Teva USA, from which Teva Ltd. derives a substantial portion of its revenue.

8. On information and belief, Teva USA acted in concert with Teva Ltd. to prepare and submit ANDA No. 212759 (the "Teva ANDA") for Teva USA's 267 and 801 mg pirfenidone tablets (the "Teva ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Teva Ltd. Following FDA approval of the Teva ANDA, Teva USA will manufacture and supply the approved generic product, which it will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Teva Ltd.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 101, *et seq.,* seeking a finding and declaratory judgment of patent infringement under 35 U.S.C. § 271(e)(2)(A) and the remedies provided under the Hatch-Waxman Act specified in 35 U.S.C. § 271(e)(4). Jurisdiction exists under 28 U.S.C. §§ 1331,

1338(a), 2201, and 2202, and venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

10. Venue is proper in this Court because, among other things, Teva USA is incorporated in the State of Delaware and therefore "resides" in this judicial district. 28 U.S.C. § 1400(b). Teva Ltd. is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

PERSONAL JURISDICTION OVER TEVA LTD.

11. Plaintiffs reallege paragraphs 1-10 as if fully set forth herein.

12. On information and belief, Teva Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

13. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, Teva Ltd., on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute the Teva ANDA Products to residents of this State upon approval of ANDA No. 212759, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through Teva USA, which is a Delaware corporation; and (4) owns Teva USA, which is a Delaware corporation.

14. Alternatively, to the extent the above facts do not establish personal jurisdiction over Teva Ltd., this Court may exercise jurisdiction over Teva Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs

with the FDA and manufacturing and selling generic pharmaceutical products through its U.S. subsidiaries that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

PERSONAL JURISDICTION OVER TEVA USA

15. Plaintiffs reallege paragraphs 1-14 as if fully set forth herein.

16. On information and belief, Teva USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

17. This Court has personal jurisdiction over Teva USA because, *inter alia*, Teva USA, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute Teva's ANDA Products to residents of this State; (3) is controlled by Defendant Teva Ltd.; (4) makes its generic drug products available in this State; (5) enjoys substantial income from sales of its generic pharmaceutical products in this State; and (6) is registered as a pharmacy wholesaler and controlled substance distributor/manufacturer with the Delaware Division of Professional Regulation.

BACKGROUND FACTS

18. Esbriet®, which contains pirfenidone as its active ingredient, is a drug used for treating patients afflicted with a rare, fatal lung disease called Idiopathic Pulmonary Fibrosis ("IPF").

19. IPF results in scarring of the lungs, which makes breathing difficult and prevents the heart, muscles, and vital organs from receiving enough oxygen to work properly. The disease can advance quickly or slowly, but eventually the lungs will harden and stop working altogether. The prognosis for IPF patients is extremely poor, with patients experiencing

significant progressive worsening of disease, and median survival of 2-5 years after diagnosis. IPF is irreversible and fatal. The cause is unknown, and there is no cure.

20. Prior to Esbriet®, no drug had been approved in the United States as safe and effective for treating IPF. Approval in the United States came only after extensive clinical research by Plaintiff InterMune, which demonstrated that Esbriet® slows progression of the disease. The FDA's approval of Esbriet® would not have been possible without the twelve years of effort by InterMune, a biopharmaceutical company that dedicated itself to developing medicines for treating IPF.

21. The FDA approved the first NDA for Esbriet® on October 15, 2014, shortly after Plaintiff InterMune was acquired by Plaintiff Genentech. This approval did not come easily. The FDA initially denied approval in 2010 following many years of research & development and multiple clinical trials. This necessitated further large-scale clinical trials and resubmission of the NDA in 2014. The clinical experimentation spanned over a decade and these combined results ultimately convinced the FDA that Esbriet® could be used safely and effectively to treat IPF patients.

22. When it first approved Esbriet®, the FDA accorded it status as a Breakthrough Therapy, and awarded Esbriet® Orphan Drug Exclusivity for treating IPF, which runs until October 15, 2021.

23. Teva now seeks to piggy-back on Plaintiffs' hard work by seeking FDA approval of the Teva ANDA that cross-references and relies upon Plaintiffs' clinical trial data. In so doing, Teva has not conducted any of the clinical trials needed to demonstrate effectiveness and safe conditions of use for its proposed Teva ANDA Product. Rather, Teva asks that the FDA

permit the Teva ANDA to rely on proprietary clinical data submitted by Plaintiffs InterMune and Genentech.

24. This action arose when Teva sent a letter notifying Plaintiffs that (i) it had filed the Teva ANDA seeking to rely on Plaintiffs' safety and efficacy data without consent, and (ii) it is seeking FDA approval to commercially launch the Teva ANDA Product before Plaintiffs' exclusive patent rights to Esbriet® have expired.

THE ASSERTED PATENTS

- U.S. Patent No. 7,566,729

25. U.S. Patent No. 7,566,729 ("the '729 patent"), entitled "Modifying Pirfenidone Treatment for Patients with Atypical Liver Function," was duly and legally issued by the United States Patent & Trademark Office ("Patent Office") on July 28, 2009, and has not expired.

26. Plaintiffs have maintained the entire right, title, and interest in the '729 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '729 patent is attached as Exhibit 1.

- U.S. Patent No. 7,635,707

27. U.S. Patent No. 7,635,707 ("the '707 patent"), entitled "Pirfenidone Treatment for Patients with Atypical Liver Function," was duly and legally issued by the Patent Office on December 22, 2009, and has not expired.

28. Plaintiffs have maintained the entire right, title, and interest in the '707 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '707 patent is attached as Exhibit 2.

- U.S. Patent No. 7,767,700

29. U.S. Patent No. 7,767,700 ("the '700 patent"), entitled "Method of Providing Pirfenidone Therapy to a Patient," was duly and legally issued by the Patent Office on August 3, 2010, and has not expired.

30. Plaintiffs have maintained the entire right, title, and interest in the '700 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '700 patent is attached as Exhibit 3.

- U.S. Patent No. 7,816,383

31. U.S. Patent No. 7,816,383 ("the '383 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on October 19, 2010, and has not expired.

32. Plaintiffs have maintained the entire right, title, and interest in the '383 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '383 patent is attached as Exhibit 4.

- U.S. Patent No. 7,910,610

33. U.S. Patent No. 7,910,610 ("the '610 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on March 22, 2011, and has not expired.

34. Plaintiffs have maintained the entire right, title, and interest in the '610 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '610 patent is attached as Exhibit 5.

- U.S. Patent No. 8,013,002

35. U.S. Patent No. 8,013,002 ("the '002 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on September 6, 2011, and has not expired.

36. Plaintiffs have maintained the entire right, title, and interest in the '002 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '002 patent is attached as Exhibit 6.

- U.S. Patent No. 8,084,475

37. U.S. Patent No. 8,084,475 ("the '475 patent"), entitled "Pirfenidone Therapy and Inducers of Cytochrome P450," was duly and legally issued by the Patent Office on December 27, 2011, and has not expired.

38. Plaintiffs have maintained the entire right, title, and interest in the '475 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '475 patent is attached as Exhibit 7.

- U.S. Patent No. 8,318,780

39. U.S. Patent No. 8,318,780 ("the '780 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on November 27, 2012, and has not expired.

40. Plaintiffs have maintained the entire right, title, and interest in the '780 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '780 patent is attached as Exhibit 8.

- U.S. Patent No. 8,383,150

41. U.S. Patent No. 8,383,150 ("the '150 patent"), entitled "Granulate Formulation of Pirfenidone and Pharmaceutically Acceptable Excipients," was duly and legally issued by the Patent Office on February 26, 2013, and has not expired.

42. Plaintiffs have maintained the entire right, title, and interest in the '150 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '150 patent is attached as Exhibit 9.

- U.S. Patent No. 8,420,674

43. U.S. Patent No. 8,420,674 ("the '674 patent"), entitled "Method of Providing Pirfenidone Therapy to a Patient," was duly and legally issued by the Patent Office on April 16, 2013, and has not expired.

44. Plaintiffs have maintained the entire right, title, and interest in the '674 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '674 patent is attached as Exhibit 10.

- U.S. Patent No. 8,592,462

45. U.S. Patent No. 8,592,462 ("the '462 patent"), entitled "Pirfenidone Treatment for Patients with Atypical Liver Function," was duly and legally issued by the Patent Office on November 26, 2013, and has not expired.

46. Plaintiffs have maintained the entire right, title, and interest in the '462 patent throughout the period of Defendants' infringement. A copy of the '462 patent is attached as Exhibit 11.

- U.S. Patent No. 8,609,701

47. U.S. Patent No. 8,609,701 ("the '701 patent"), entitled "Pirfenidone Treatment for Patients with Atypical Liver Function," was duly and legally issued by the Patent Office on December 17, 2013, and has not expired.

48. Plaintiffs have maintained the entire right, title, and interest in the '701 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '701 patent is attached as Exhibit 12.

- U.S. Patent No. 8,648,098

49. U.S. Patent No. 8,648,098 ("the '098 patent"), entitled "Pirfenidone Therapy and Inducers of Cytochrome P450," was duly and legally issued by the Patent Office on February 11, 2014, and has not expired.

50. Plaintiffs have maintained the entire right, title, and interest in the '098 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '098 patent is attached as Exhibit 13.

- U.S. Patent No. 8,754,109

51. U.S. Patent No. 8,754,109 ("the '109 patent"), entitled "Pirfenidone Therapy and Inducers of Cytochrome P450," was duly and legally issued by the Patent Office on June 17, 2014, and has not expired.

52. Plaintiffs have maintained the entire right, title, and interest in the '109 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '109 patent is attached as Exhibit 14.

- U.S. Patent No. 8,778,947

53. U.S. Patent No. 8,778,947 ("the '947 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on July 15, 2014, and has not expired.

54. Plaintiffs have maintained the entire right, title, and interest in the '947 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '947 patent is attached as Exhibit 15.

55. The '729, '707, '700, '383, '610, '002, '475, '780, '150, '674, '462, '701, '098, '109, and '947 patents are referred to collectively herein as the "Asserted Patents."

ACTS GIVING RISE TO THIS ACTION

56. Plaintiff Genentech is the holder of NDA No. 208780 (the "Genentech NDA") by which the FDA granted approval for 267, 534, and 801 mg pirfenidone tablets for treating IPF. Genentech holds the exclusive right to market these tablets in the United States under the trademark Esbriet®.

57. Esbriet® tablets and the use of Esbriet® tablets in accordance with its FDA-approved label are covered by one or more claims of the Asserted Patents.

58. The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the Asserted Patents in connection with Esbriet® tablets.

59. By letter dated December 11, 2018 (the "Notice Letter") Teva notified Plaintiffs that it had submitted the Teva ANDA to the FDA, seeking approval for commercial manufacture, use, and sale of the Teva ANDA Product in the United States prior to the expiration of the Asserted Patents.

60. In the Notice Letter, Teva notified Plaintiffs that, as a part of its ANDA, it had filed a certification under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Asserted Patents (the "Paragraph IV Certification"), that those patents are allegedly invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of the Teva ANDA Product in the United States.

61. By filing the Teva ANDA, Teva has necessarily represented to the FDA that the Teva ANDA Product will have the same pirfenidone active ingredient, route of administration, dosage form, and dosage strengths as Plaintiffs' FDA-approved Esbriet® tablets, and will be bioequivalent.

62. Teva's Notice Letter contained an offer of confidential access ("OCA"), the terms of which the parties attempted to negotiate in good faith in an effort to reach a mutually acceptable agreement, and under which the Teva ANDA would be provided to Plaintiffs. The parties were unable to reach an agreement on the OCA terms because Teva's proposed OCA contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the proposed Teva OCA contained a broad patent prosecution and regulatory work bar (including but not limited to a patent-related bar and an FDA bar), which, among other things, does not have a carve-out for inter partes reviews or other adversarial proceedings. The proposed Teva OCA unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside scientific consultants. The restrictions Teva placed on access to ANDA No. 212759 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, **as would apply had a protective order been entered for the purpose of protecting trade secrets and other**

confidential business information" (emphasis added). Plaintiffs have not been able to evaluate the Teva ANDA. Plaintiffs require discovery from Teva in this action.

63. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Notice Letter.

COUNT I

INFRINGEMENT OF THE '729 PATENT

64. Plaintiffs reallege paragraphs 1 to 63 as if fully set forth herein.

65. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '729 patent.

66. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '729 patent.

67. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '729 patent infringed at least one of the claims of the '729 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

68. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '729 patent would further infringe at least one claim of the '729 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

69. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly

infringe at least one of the claims of the '729 patent either literally or under the doctrine of equivalents.

70. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '729 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '729 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

71. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '729 patent, either literally or under the doctrine of equivalents.

72. On information and belief, Teva had knowledge of the '729 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '729 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '729 patent.

73. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '729 patent, either literally or under the doctrine of equivalents.

74. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '729 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

INFRINGEMENT OF THE '707 PATENT

75. Plaintiffs reallege paragraphs 1 to 74 as if fully set forth herein.

76. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '707 patent.

77. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '707 patent.

78. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '707 patent infringed at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

79. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '707 patent would further infringe at least one claim of the '707 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

80. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '707 patent either literally or under the doctrine of equivalents.

81. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '707 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of

the '707 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

82. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents.

83. On information and belief, Teva had knowledge of the '707 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '707 patent.

84. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents.

85. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '707 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III

INFRINGEMENT OF THE '700 PATENT

86. Plaintiffs reallege paragraphs 1 to 85 as if fully set forth herein.

87. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '700 patent.

88. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '700 patent.

89. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '700 patent infringed at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

90. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '700 patent would further infringe at least one claim of the '700 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

91. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '700 patent either literally or under the doctrine of equivalents.

92. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '700 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

93. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents.

94. On information and belief, Teva had knowledge of the '700 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '700 patent.

95. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents.

96. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '700 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV

INFRINGEMENT OF THE '383 PATENT

97. Plaintiffs reallege paragraphs 1 to 96 as if fully set forth herein.

98. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '383 patent.

99. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '383 patent.

100. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '383 patent infringed at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

101. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '383 patent would further infringe at least one claim of the '383 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

102. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '383 patent either literally or under the doctrine of equivalents.

103. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '383 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

104. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents.

105. On information and belief, Teva had knowledge of the '383 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '383 patent.

106. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents.

107. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '383 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V

INFRINGEMENT OF THE '610 PATENT

108. Plaintiffs reallege paragraphs 1 to 107 as if fully set forth herein.

109. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '610 patent.

110. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '610 patent.

111. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '610 patent infringed at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

112. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '610 patent would further infringe at least one claim of the '610 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

113. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '610 patent either literally or under the doctrine of equivalents.

114. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '610 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

115. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents.

116. On information and belief, Teva had knowledge of the '610 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '610 patent.

117. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents.

118. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '610 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI

INFRINGEMENT OF THE '002 PATENT

119. Plaintiffs reallege paragraphs 1 to 118 as if fully set forth herein.

120. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '002 patent.

121. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '002 patent.

122. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '002 patent infringed at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

123. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '002 patent would further infringe at least one claim of the '002 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

124. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '002 patent either literally or under the doctrine of equivalents.

125. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '002 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

126. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents.

127. On information and belief, Teva had knowledge of the '002 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '002 patent.

128. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents.

129. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '002 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VII

INFRINGEMENT OF THE '475 PATENT

130. Plaintiffs reallege paragraphs 1 to 129 as if fully set forth herein.

131. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '475 patent.

132. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '475 patent.

133. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '475 patent infringed at least one of the claims of the '475 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

134. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '475 patent would further infringe at least one claim of the '475 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

135. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '475 patent either literally or under the doctrine of equivalents.

136. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '475 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of

the ‘475 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

137. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the ‘475 patent, either literally or under the doctrine of equivalents.

138. On information and belief, Teva had knowledge of the ‘475 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others’ direct infringement of at least one of the claims of the ‘475 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the ‘475 patent.

139. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the ‘475 patent, either literally or under the doctrine of equivalents.

140. If Defendants’ marketing and sale of the Teva ANDA Product prior to expiration of the ‘475 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII

INFRINGEMENT OF THE ‘780 PATENT

141. Plaintiffs reallege paragraphs 1 to 140 as if fully set forth herein.

142. Teva’s Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the ‘780 patent.

143. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '780 patent.

144. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '780 patent infringed at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

145. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '780 patent would further infringe at least one claim of the '780 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

146. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '780 patent either literally or under the doctrine of equivalents.

147. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '780 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

148. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents.

149. On information and belief, Teva had knowledge of the '780 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '780 patent.

150. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents.

151. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '780 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IX

INFRINGEMENT OF THE '150 PATENT

152. Plaintiffs reallege paragraphs 1 to 151 as if fully set forth herein.

153. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '150 patent infringed at least one of the claims of the '150 patent, including but not limited to claims 1 and 27, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

154. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '150 patent would further infringe at least one claim of the '150 patent, including but not limited to claims 1 and 27, under 35 U.S.C. §§ 271 (a), (b), and/or (c), either literally or

under the doctrine of equivalents because, *inter alia*, the Teva ANDA Product contains the same components recited in claim 1 and use of the Teva ANDA product in accordance with its associated labeling would infringe at least claim 27.

155. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '150 patent either literally or under the doctrine of equivalents.

156. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '150 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

157. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents.

158. On information and belief, Teva had knowledge of the '150 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '150 patent.

159. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents.

160. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '150 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT X

INFRINGEMENT OF THE '674 PATENT

161. Plaintiffs reallege paragraphs 1 to 152 as if fully set forth herein.

162. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '674 patent.

163. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '674 patent.

164. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '674 patent infringed at least one of the claims of the '674 patent either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

165. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '674 patent would further infringe at least one claim of the '674 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

166. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '674 patent either literally or under the doctrine of equivalents.

167. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '674 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '674 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

168. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '674 patent, either literally or under the doctrine of equivalents.

169. On information and belief, Teva had knowledge of the '674 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '674 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '674 patent.

170. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '674 patent, either literally or under the doctrine of equivalents.

171. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '674 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XI

INFRINGEMENT OF THE '462 PATENT

172. Plaintiffs reallege paragraphs 1 to 171 as if fully set forth herein.

173. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '462 patent.

174. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '462 patent.

175. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '462 patent infringed at least one of the claims of the '462 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

176. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '462 patent would further infringe at least one claim of the '462 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

177. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '462 patent either literally or under the doctrine of equivalents.

178. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '462 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '462 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

179. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '462 patent, either literally or under the doctrine of equivalents.

180. On information and belief, Teva had knowledge of the '462 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '462 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '462 patent.

181. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '462 patent, either literally or under the doctrine of equivalents.

182. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '462 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XII

INFRINGEMENT OF THE '701 PATENT

183. Plaintiffs reallege paragraphs 1 to 182 as if fully set forth herein.

184. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '701 patent.

185. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '701 patent.

186. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '701 patent infringed at least one of the claims of the '701 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

187. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '701 patent would further infringe at least one claim of the '701 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

188. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '701 patent either literally or under the doctrine of equivalents.

189. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '701 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of

the '701 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

190. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '701 patent, either literally or under the doctrine of equivalents.

191. On information and belief, Teva had knowledge of the '701 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '701 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '701 patent.

192. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '701 patent, either literally or under the doctrine of equivalents.

193. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '701 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIII

INFRINGEMENT OF THE '098 PATENT

194. Plaintiffs reallege paragraphs 1 to 193 as if fully set forth herein.

195. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '098 patent.

196. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '098 patent.

197. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '098 patent infringed at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

198. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '098 patent would further infringe at least one claim of the '098 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

199. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '098 patent either literally or under the doctrine of equivalents.

200. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '098 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

201. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents.

202. On information and belief, Teva had knowledge of the '098 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '098 patent.

203. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents.

204. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '098 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIV

INFRINGEMENT OF THE '109 PATENT

205. Plaintiffs reallege paragraphs 1 to 204 as if fully set forth herein.

206. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '109 patent.

207. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '109 patent.

208. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '109 patent infringed at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

209. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '109 patent would further infringe at least one claim of the '109 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

210. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '109 patent either literally or under the doctrine of equivalents.

211. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '109 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

212. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents.

213. On information and belief, Teva had knowledge of the '109 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '109 patent.

214. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents.

215. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '109 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XV

INFRINGEMENT OF THE '947 PATENT

216. Plaintiffs reallege paragraphs 1 to 215 as if fully set forth herein.

217. Teva's Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Teva ANDA Product will not infringe each claim of the '947 patent.

218. On information and belief, Teva does not deny that the Teva ANDA Product will infringe at least certain claims of the '947 patent.

219. Defendants' submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States prior to the expiration of the '947 patent infringed at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

220. Defendants' manufacture, use, offer to sell, or sale of the Teva ANDA Product in the United States or importation of the Teva ANDA Product into the United States during the term of the '947 patent would further infringe at least one claim of the '947 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

221. On information and belief, the Teva ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '947 patent either literally or under the doctrine of equivalents.

222. On information and belief, the use of the Teva ANDA Product constitutes a material part of at least one of the claims of the '947 patent; Defendants know that the Teva ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents; and the Teva ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

223. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product would contributorily infringe at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents.

224. On information and belief, Teva had knowledge of the '947 patent and, by its promotional activities and package inserts for the Teva ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '947 patent.

225. On information and belief, the offering to sell, sale, and/or importation of the Teva ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents.

226. If Defendants' marketing and sale of the Teva ANDA Product prior to expiration of the '947 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

* * *

227. Defendants' activities, as alleged herein, were undertaken with knowledge of the Asserted Patents and without a good faith belief that they are not infringing those patents. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the Asserted Patents were infringed by Defendants' submission of the Teva ANDA, either literally or under the doctrine of equivalents, and are not invalid or unenforceable, and that Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States the Teva ANDA Product will infringe the claims of the Asserted Patents, either literally or under the doctrine of equivalents.

2. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the Teva ANDA shall be a date which is not earlier than the latest expiration date of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An Order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Teva ANDA Product until after the latest expiration date of the Asserted

Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, to Plaintiffs if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Teva ANDA Product prior to the latest expiration date of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

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January 24, 2019